

DOCKET NO.: UPAP-0345
PATENT APPLICATION

SERIAL NO.: 09/359,975
FILED: JULY 23, 1999

REMARKS

Status of the Claims

Claims 58-121 are in the application.

Claims 58, 59, 62-64, 67-72, 74-76, 84-86, 94-96, and 115-121 have been rejected.

Claims 60, 61, 65, 66, 73, 77-83, 87-93, and 97-114 have been withdrawn from consideration.

By way of this amendment, claims 60-62, 65, 66, 73, 74, 77-83, 87-93, and 97-114 have been cancelled, claims 58, 63, 67, 75, 84, and 94 have been amended, and new claims 122 to 147 have been added.

Upon entry of this amendment, claims 58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96, and 115-147 will be pending.

Summary of the Amendment

In this amendment, Applicants affirm the provisional election of claim groups I and IV made in the telephone interview of January 11, 2000.

Claims 60-62, 65, 66, 73, 74, 77-83, 87-93, and 97-114 have been cancelled without prejudice. Claims 60, 61, 65, 66, 73, 77-83, 87-93, and 97-114 are drawn to non-elected matter; claims 62 and 74 are redundant in light of the claim amendments herein.

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New claims 122-147 have been added to specifically define several embodiments of the invention. Support for the new claims can be found throughout the specification and in the claims as originally filed, such as, for example, claims 58, 67, and 115. No new matter has been added.

Claims 58, 63, 67, 75, 84, and 94 have been amended to correct dependencies which are no longer proper in light of the claim cancellations herein. Claim 58 has also been amended to clarify a proper antecedent. Support for the amended claims can be found, for example, in the claims as originally filed. No new matter has been added.

Finally, in this amendment an abstract has been added to the specification. Applicants note that an abstract was provided in the parent PCT application of this U.S. national stage application. The new abstract is substantially identical to that which was originally filed.

Election/Restriction

The Examiner is thanked for the courtesy of a telephone interview with the undersigned on January 11, 2000, in which the present restriction requirement was discussed. Applicants affirm the election to restrict the examination to claim groups I and IV. Following entry of the amendment, all the claims in the application, that is, claims 58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96, and 115-121, and new claims 122-147, are believed to be within the elected groups.

Objection under 37 C.F.R. § 1.75(c)

Claims 62, 74, 84, and 94

Claims 62, 74, 84, and 94 were objected to as being improperly dependent from claims withdrawn from consideration. Claims 62 and 74 have been cancelled without prejudice in this amendment; thus, this objection is no longer applicable to claims 62 and 74. Claims 84 and 94 have been amended to remove their dependency on claims that are cancelled herein. Applicants note that the scope of claims 84 and 94 as amended remains unchanged from their original scope.

As amended, the claims are in compliance with 37 C.F.R. § 1.75(c).

Rejection under 35 U.S.C. §112, first paragraph

Claims 58, 59, 62-64, 67-72, 74-76, 84-86, 94-96, and 115-121

Claims 58, 59, 62-64, 67-72, 74-76, 84-86, 94-96, and 115-121 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in such a way as to enable one skilled in the art to make and use the invention. It is asserted that the specification does not provide enablement for any of the claimed nucleotide function enhancers except bupivacaine, and that undue experimentation would be required to determine whether the other claimed nucleotide function enhancers are in fact operational.

First, Applicants respectfully maintain that this rejection is procedurally improper and should therefore be withdrawn upon reconsideration. In this respect, the following statement from *In re Marzocchi*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971), is noteworthy:

The only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirements of the first paragraph of § 112 **unless there is reason to doubt the objective truth of the statements contained therein** which must be relied upon for enabling support. (Emphasis added)

Any assertion by the Patent Office that an enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974).

No such evidence or reasoning has been provided. The Office Action's bare assertion that structures besides bupivacaine are not enabled is an insufficient basis for questioning the enablement of the claimed invention. The statement that non-routine, trial and error experimentation would be required to practice the invention is not supported by any facts or argument, and is therefore merely conclusory. Accordingly, the rejection is improper.

Applicants further respectfully contend that the silence of the prior art is not dispositive of the question of enablement. The fact that an invention is new and non-obvious

does not render it non-enabled. The determination of adequacy of enablement requires that the contents of the disclosure be considered in addition to that which is already known by practitioners of the art. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." MPEP § 2164.01, quoting *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The simple observation that the prior art does not enable the claimed compounds is, accordingly, not a proper foundation for a rejection based on lack of enablement.

Since the Patent Office has not carried its procedural burden of setting forth facts and reasoning showing why the claims are not enabled, Applicants respectfully submit that this rejection should be withdrawn upon reconsideration

Similarly, the Office Action observes that some of the claimed compounds have not been demonstrated by working examples. Lack of working examples, however, is also an insufficient basis for challenging the enablement of an invention. On this subject, MPEP § 2164.02 is pertinent:

Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. ... An applicant need not have actually reduced the invention to practice prior to filing. ... The Court held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." ... The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled

in the art will be able to practice it without an undue amount of experimentation.

To elaborate, the enablement requirement of 35 U.S.C. §112 is satisfied so long as a disclosure contains sufficient information that persons of ordinary skill in the art having the disclosure before them would be able to make and use the invention. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) (the legal standard for enablement under section 112 is whether one skilled in the art would be able to practice the invention without undue experimentation). In fact, the sole test of enablement is whether a person of ordinary skill in the art can make and use the claimed invention without undue experimentation. *See, e.g.*, MPEP § 2164.01. Moreover, “[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.” *Id.*, citations omitted.

Applicants respectfully disagree with the contention in the Office Action that a trial-and-error method is *per se* undue experimentation. To the contrary, Applicants respectfully submit that the art of pharmaceutical discovery is very advanced, and those skilled in the art, once armed with the teachings in this specification, would certainly readily contemplate methods of determining whether the compounds claimed in this application do in actuality operate as nucleotide function enhancers. Since even complex and copious experimentation is not undue if it is routine in the art, the claims are enabled, and therefore the Applicants respectfully maintain that the rejection should be withdrawn upon reconsideration.

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Applicants respectfully urge that claims 58, 59, 62-64, 67-72, 74-76, 84-86, 94-96, and 115-121 are in compliance with the requirements of 35 U.S.C. §112. Applicants respectfully request that the rejections of claims 58, 59, 62-64, 67-72, 74-76, 84-86, 94-96, and 115-121 under 35 U.S.C. §112, first paragraph, be withdrawn.

Rejection under 35 U.S.C. §112, second paragraph

Claims 58, 59, and 62-64

Claim 58 and all dependent claims have been rejected under 35 U.S.C. §112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claim 58 has been amended to more clearly define the subject matter of the claims. The proper antecedent of "polynucleotide function enhancer" in line 5 of claim 58 is now clearly the same phrase in line 2. Applicants have with this amendment corrected an obvious typographical error. No new matter has been added.

As amended, the claims are clear. When read as amended by Applicants, the subject matter in the claims is now clear and definite and in compliance with the second paragraph of 35 U.S.C. §112.

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Conclusion

Applicants respectfully request that claims 58, 59, 63, 64, 67-72, 75, 76, 84-86, 94-96,
and 115-147 be allowed. A Notice of Allowance is earnestly solicited.

Respectfully Submitted,



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